HIPAA Basics for Clinical Research

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Presenter

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Caution!

- HIPAA is huge…
- State laws may trump or stand side by side with federal law, so your state may handle certain data sharing in a different way that I'm describing today
- HIPAA must be harmonized with other HHS and FDA requirements; these are not always consistent, which means that sometimes HIPAA will require more strenuous or specific data protections than the other laws do
- Sometimes the answer to a HIPAA question is fact-specific rather than general

Agenda

- HIPAA Overview
- Key Terminology and Approach
- Researchers' Access, Use, Disclosure of PHI
- Activities Preparatory to Research
- Research on Decedent's Information
- Authorizations, Waivers, and Alterations
- PHI or Non-PHI in Research
- IRBs and Privacy Boards
- Other Rules Still Apply
- Resource Guide

What is HIPAA?

- HIPAA is the Health Insurance Portability and Accountability Act of 1996
- It was intended to support and address:
  - Health insurance portability and certain market reforms
  - Standardizing data exchange transactions
  - Public concerns over potential abuses of health information privacy
  - Equal standards of privacy protection for research regardless whether it is governed by human subject regulations
- HIPPA has evolved over time to incorporate measures to enhance previous requirements governing the privacy and security of health information (e.g., “GINA,” the Genetic Information Nondiscrimination Act)

Key Terms

- “PHI”
- “Covered Entity”
- “Business Associate”
- “P&P”
- “Use”
- “Disclosure”
- “TPO”
- “Minimum Necessary Rule”
- “Accounting of Disclosures”
- “Authorization”
- “IRB” and “Privacy Board”

Who is Subject to HIPAA?

- Covered Entities
  - Health care providers that transmit health information electronically using “Standard Transactions” (e.g., claims, eligibility queries…)
  - Health Plans and Health Plan Issuers
  - Health Care Clearing Houses

Who Else is Subject to HIPAA?

- Business Associates
  - Researchers are not Business Associates simply because they are doing research, even if the research takes place at a Covered Entity location
  - Researchers might be Business Associates if they do certain services, activities, or functions on behalf of the Covered Entity (e.g., data de-identification)
- Researchers are not necessarily subject to HIPAA, unless they are also a Covered Entity or the employee of a Covered Entity

When Can Researchers Access, Use, or Disclose PHI?

- If the subject of the PHI has granted permission in writing via a valid HIPAA Authorization Form
- If an IRB or Privacy Board has granted a waiver or alteration of the standard Authorization process for the study
- If the PHI is contained in a Limited Data Set, governed by a Data Use Agreement between the Researcher and the Covered Entity who is going to disclose the PHI
- If the Informed Consent document includes the Authorization language (in full or modified with IRB/Privacy Board approval)
- (De-identified PHI is always an option)

Researchers' Representations Preparatory to Research

- Before gaining access to a Covered Entity's PHI, a Researcher must "represent" that:
  - The use or disclosure of PHI is sought solely to prepare a research protocol or for similar preparatory purposes
    - E.g., are there enough records of the right type to continue to pursue the research project?
  - He or she will not remove PHI from the Covered Entity during the review
  - The PHI the Researcher seeks to use or access is necessary for research purposes

Activities Preparatory to Research

- Covered Entities can release PHI to the Researcher (once the necessary representations have been received) for example, to develop a study protocol, develop a research hypothesis, or to aid in study recruitment
  - This includes identifying potential candidates, but does NOT include contacting the candidates
  - Contact is permissible if the Researcher is an employee of the Covered Entity and contacts the candidate as part of health care operations (e.g. to discuss treatment alternatives) and consequently obtains an Authorization

Activities Preparatory to Research, Cont.

- The Covered Entity might also elect to hire a Business Associate (who might also be the Researcher), to assist with contacting the candidates on behalf of the Covered Entity to obtain Authorizations
- In the alternative, if the Researcher can show the Covered Entity that an IRB or Privacy Board has partially or fully waived the Authorization requirement to allow disclosure of PHI for recruitment, the Covered Entity could disclose the PHI needed for the Researcher to contact the candidate

Research on Decedents' Information

- Access to this type of PHI is permissible if the Researcher "represents" that the use or disclosure is sought solely for research on the PHI of decedents (not the living relatives)
- The Researcher may be asked by Covered Entity to provide documentation on the death of the study subjects
- The Researcher will also need to "represent" that the PHI sought is necessary for research purposes
- No Authorization, waiver or alteration of the Authorization is required from IRB/Privacy Board under these circumstances

45 CFR 164.512(i)(iii)

I Want to Create a Records Repository for Research Use

- Under the HIPAA Privacy Rule, there are two separate activities under consideration if you want to create a record repository for research use:
  - The use or disclosure of PHI to create the database is the first activity
  - The subsequent uses or disclosures of PHI in the database for a particular research protocol is a separate activity
  - Each of these activities requires separate Authorization (or waiver, or alteration)

Records Repositories

- The Privacy Rule allows Covered Entities to gather information from patients to perform “TPO” (Treatment, Payment, and Health Care Operations)
- Covered Entities can enter this information into their own databases without patient authorization
- Such databases continue to be updated and maintained and are available to Researchers, although HIPAA has imposed access requirements

Research Record Repository, Continued

- HIPAA expects an Authorization for each “activity” (unless waived or altered each time by an IRB or Privacy Board)
- The Authorization must tell the study subject what uses or disclosures will occur
- Obtain an Authorization, a waiver, or alteration upon creation and then again upon access by each study

Research Repository, Continued

- Obtain IRB or Privacy Board approval for the alteration of the Authorization requirement plus then obtain the altered Authorization from the subject
- Provide the Covered Entity with the necessary Researcher's representations
- Use a Limited Data Set with a Data Use Agreement

Uses and Disclosures for Research Purposes

- Covered Entities may use or disclose PHI for research regardless of the funding of the research provided that
  - The Covered Entity has obtained documentation that an alteration to, or waiver of, the patient authorization was approved by the IRB or a Privacy Board
  - “Documentation” means a statement identifying the IRB or Privacy Board granting the approval, and the date the approval was granted

HIPAA's Order of Preference

- Obtain an individual's written authorization on a valid HIPAA Authorization Form
- Use de-identified PHI (i.e., it isn't PHI any more)
- Use a LDS with a DUA
- Obtain an IRB or Privacy Board's approval for a waiver or alteration of the Authorization

Let's discuss what is required if we choose any of the above options.

Authorizations and Informed Consents

- The documents serve different purposes.
- The purpose of a HIPAA Authorization is for the subject to specify which PHI may be used or disclosed, to whom, for what purpose, and for what time period
- There are certain core elements that must be included in an Authorization in order for it to be valid
- Informed Consent documents are used to describe the study and its risks as a whole, and allows the patient to agree to participate in the study

Authorizations

- If a standard HIPAA Authorization is used, it may specify an end (e.g., “the end of the research project” or “12/31/2015”), or specify that there will be no end date or event
- Generally obtained at the beginning of the study at the time the informed consent is gathered
- Do not use or disclose PHI for any other reason than those listed on the Authorization
- Following the HITECH Act implementation, the Authorization to use or disclose PHI for a research study does not have to be study-specific, if it is clearly allowing for use in future research studies

Does the IRB Have to Review Authorizations?

- An IRB would generally only be expected to review the language of an Authorization if it was incorporated into the Informed Consent document
- If the Authorization is a stand-alone document, the IRB might still need to review the document if that were required by the IRB's written procedures, but this expectation comes from FDA regulations, not HIPAA

HIPAA Views of Waiving Authorizations

- HIPAA would prefer that a study subject sign an Authorization if he or she is being asked to sign an informed consent document
- According to HHS, a waiver of the Authorization requirement is more applicable to a retrospective chart review type of study
- HIPAA would further expect that the PHI accessed under a waived Authorization would tightly follow the Minimum Necessary Rule

Authorizations in a Research Setting

- Researchers can obtain a “compound authorization” from study subjects
- Certain types of compound authorizations are permissible under the Privacy Rule, while others are “alterations” that need IRB or Privacy Board approval
  - In a compound Authorization, the subject could authorize use and disclosure of his/her PHI in combination with other types of written permission (such as an informed consent document) for the same or another research study or studies
  - A compound Authorization might also include multiple activities such as collecting information for a study, and storing the PHI in a central repository for future research 45 CFR 164.508(B)(3)(i)

What if the Study Subject Revokes His/Her Authorization

- The study subject has the legal right to revoke his or her authorization at any time and for any reason
- PHI gathered prior to the revocation of the Authorization can't be further used or disclosed after revocation except to the extent necessary to protect the integrity of the research
  - E.g., to account for the withdrawal of the subject, to investigate scientific misconduct, report adverse events, or incorporate information into a marketing application to the FDA

First Way to De-Identify PHI

Strip out these “identifiers” as listed at 45 CFR 164.514(b)(2)

- Patient and family member names (including just initials)
- Geographic information more precise than a state
- Any date (except year)
- Medical Record Number
- Phone Number
- Fax Number
- SSN
- Email Address
- Health Plan ID
- Account Number
- URLs
- Facial Photo
- IP Address
- Photos
- Vehicle ID
- Employer Name
- “Any other” Unique ID
- Certificate or License No.
- Biometric ID
- Device ID

Caveat – Method 1

- All of the listed identifiers are removed AND the Covered Entity doesn't have actual knowledge that the info can be used, alone or in combination with other information, to identify the subject of the PHI

Second Way to De-Identify PHI

- Have a “qualified statistician” determine that the risk is very small that the information could be used alone or in combination with other reasonably available information by the intended recipient to identify the subject of the PHI. The statistician must document the methods and results of the analysis that permitted him/her to draw this conclusion
- A Qualified Statistician is “a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable”

“Coding” to Re-Identify Data

- Covered Entities may assign and retain with the De-ID data a code or other means of re-identifying the record, as long as:
  - The code is not derived from the actual PHI (e.g. taking the subject’s Social Security Number and putting it in a different order)
  - The code can’t be used to re-identify the subject
  - The code is not disclosed except to actually re-identify the subject
  - The Covered Entity doesn’t reveal its method of re-identifying the information
  - The code is not disclosed except to actually re-identify the subject
  - The Covered Entity doesn’t reveal its method of re-identifying the information
- Recommendation: use a randomly-generated code for this purpose

Limited Data Sets and Data Use Agreements

- If only certain identifiers are necessary, a LDS is an option
- An LDS contains nearly de-identified PHI (but is still PHI), with only address info (not PO Box, street number or name), dates such as admission/discharge dates, and “other unique identifiers” that are not direct identifiers
- DUAs must be signed between the Researcher and the Covered Entity establishing permitted uses and protections

IRB or Privacy Board – Waiver or Alteration Approval Process

- IRB *AND* Privacy Board approval is not needed-just one or the other
  - The location of the IRB or Privacy Board is not pertinent
- A statement documents that the IRB follows the requirements of the Common Rule, including the normal review procedures
- The IRB or Privacy Board must review the proposed research at convened meetings at which a majority of Board members are present, including the member not affiliated with the Covered Entity or research sponsor, and for IRBs, the member with the nonscientific background.
  - The research must be approved by a majority vote

Privacy Board

- To meet HIPAA's requirements, a Privacy Board must—
  - Have at least two members
    - These members must have varying backgrounds and appropriate professional competency to review the effect of the research protocol on the subject's privacy rights and related interests
  - Includes at least one member who is not directly or indirectly affiliated with the Covered Entity, the research sponsor or CRO
  - Does not include a member with a conflict of interest with such study project

45 CFR 164.512(i)(1)(i)(B)

Institutional Review Board

- An IRB must have at least five members with varying backgrounds and professions to promote complete and adequate review of the research activities commonly conducted at the institution
- The membership should be diverse in age, gender, race, culture, focus of practice, etc.
- One member should be science-focused, one should be nonscientific, and one should be unaffiliated with the institution, even by marriage
- IRB members with a conflict of interest with the study may not participate in the review

Waiver Criteria

- The IRB or Privacy Board may grant a waiver or alteration of the HIPAA authorization requirement if all of the following (at minimum) is true:
  - The use or disclosure of PHI involves no more than a minimal risk to the privacy of the subjects based on the presence of these elements
  - There is an adequate plan to protect the identifiers from the improper use and disclosure
  - There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with the research needs
  - The research couldn't be practicably conducted without the waiver or alteration
  - The research couldn't be practicably conducted without access to and use of the PHI

Waivers, Continued

- The IRB or Privacy Board chair or designee must officially document and "sign" its findings that the criteria are met
  - The documentation should include the identity of the IRB or Privacy Board
  - The date of the review and approval
  - The specific PHI determined to be needed for the research activity
  - An explicit statement that the criteria was met for approval of the waiver or alteration of the Authorization (and if applicable, what was altered)
  - Need to document whether the regular or expedited process was used

Expedited Review Option

- An IRB or Privacy Board may use an expedited review process if the research involves no more than minimal risk to the privacy of the subjects whose PHI is being used or disclosed
- Expedited reviews are prohibited by a member of the IRB or Privacy Board that has a conflict of interest with the study under review
- If the expedited process is chosen by the IRB or Privacy Board, it is sufficient to have the review and approval completed by the Chair or its designee(s)
- IRBs are obligated to keep the other members informed of waivers or alterations of Authorizations approved during an expedited review

Other HIPAA Requirements to Remember

- The Minimum Necessary Rule applies to research studies
- Accounting of Disclosures
- Subjects' right to access study records
- Retention of documentation such as IRB or Privacy Board approvals of waivers or alterations of Authorization requirements

Reporting Adverse Events

- It does not violate HIPAA to report the minimum necessary PHI about adverse events IF one of these is true:
  - The subject's Authorization permits it
  - The Authorization requirement has been waived or altered
  - It is required by law
  - It is permitted for public health reasons, which includes reporting to a person subject to the jurisdiction of the FDA for an FDA-regulated product (i.e., the study sponsor or an FDA-Regulated IRB)
    - HIPAA views the Office for Human Research Protections (OHRP) as a public health authority

Minimum Necessary Rule

- A Covered Entity must follow the Minimum Necessary Rule when sharing PHI with a Researcher (unless there is a valid authorization signed by the study subject)
- This means that the Covered Entity may only disclose the information that is necessary to accomplish the research purpose
- If the IRB/Privacy Board has granted a waiver or alteration of the Auth, the Covered Entity can rely on the description of needed PHI in those documents to be the Minimum Necessary

Accounting of Disclosures

- Accountings of Disclosures apply to research studies conducted under a waiver or alteration of the Authorization process unless the disclosure was into a Limited Data Set with a Data Use Agreement
  - Disclosures of 50+ individuals can be “general” rather than specific
  - What PHI was disclosed, to whom (including the address if known), when, and for what purpose (e.g., the protocols for which the disclosure was made)
  - Subjects may request the Covered Entity for assistance in contacting the Sponsor of the study and/or the Researcher associated with a protocol after receiving the Accounting of Disclosures

Subjects' Access to Study Records

- A study subject is entitled to request access to and copies of any PHI that is part of the Covered Entity's "Designated Record Set" or DRS
- The DRS includes any record that is used to make a decision (e.g., billing, medical, payment, enrollment) about the subject of the information
- If the subject's study-related information is in his or her medical record, that information must be made available to the subject upon request, unless the subject waived access rights until the end of the research study as part of the informed consent document

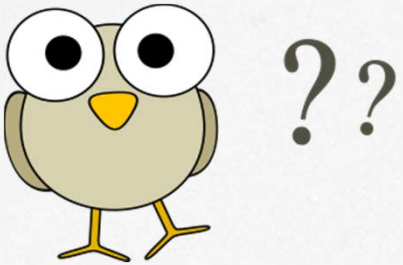
Access to Study Records, Cont.

- Follow your policies and procedures regarding access to PHI
- Coordinate responses to requests for such access with your privacy officer and your medical records department, and if needed with your legal counsel, to be sure that you are following all of the necessary requirements with institutional polices as well as the Privacy Rule

Resource Guide

Minimum Necessary Rule - 45 CFR 164.502(b) and 164.514(d)	Authorization Requirements - 45 CFR 164.508
Uses and Disclosures of PHI for Research - 45 CFR 164.512(i)	Limited Data Sets/Data Use Agreements - 45 CFR 164.514(e)
Notice of Privacy Practices - 45 CFR 164.520(c)(2)	Accounting of Disclosures (general and specific) - 45 CFR 164.528(b)(4)
HHS 45 CFR 46.117(a) and FDA 21 CRF 50.27(a) - IRB review of Authorizations	HHS Website - http://www.hhs.gov/ocr/privacy/hipaa/faq/research_disclosures/317.html
HHS and FDA Protection of Human Subjects Regulations at 45 CFR Part 46 and 21 CFR Parts 50 and 56 (respectively) - For research involving development or use of research repositories and associated data	

Questions?



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